91 Rylander Blvd. Unit 7, Suite 266
Toronto, Ontario M1B 5M5
Tel: (905) 837-1302, Fax: (905) 831-6611
Toll Free 1-877 766 6604
Web site: www.canadiancourier.org
E-mail: pcahley@canadiancourier.org

United States Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Via e-mail to:
fdadockets@oc.fda.gov

May 14, 2004

Subject: CCMA Statement on the implementation procedures enacted by the U.S. Food and Drug Administration (FDA) pursuant to the U.S. Bioterrorism Act (BTA) legislation. Regarding: FDA Docket 2002N-0278

These comments are submitted by the Canadian Courier & Messenger Association (CCMA), after review of implementation procedures enacted by the US Food and Drug Administration (FDA) pursuant to the US Bioterrorism Act (BTA) legislation.

Market Profile
To give you some background on our organization, the CCMA is the trade association representing time sensitive delivery service company operations of all types and sizes across Canada by providing professional, informed and proactive representation and information on common issues. Our members include; large firms with global delivery networks, such as DHL, Emery, FedEx, Purolator, TNT and United Parcel Service, overnight transborder integration firms, mid size local and regional delivery firms with strong area distribution networks and smaller local firms such as same day and messenger companies maintaining an extensive stake in the time sensitive shipping business.

The Canadian Courier market is estimated to be worth over 5 billion dollars annually and translates to the movement of almost 2 million packages per day. This vital sector of our economy is made up of approximately 2,400 courier companies employing nearly 55,000 people utilizing 14,000 delivery vehicles, hundreds of aircraft and over 400 local sortation centers. Worldwide, CCMA members have operations in over 200 countries; move more than 20 million packages each day; employ more than 800,000 people; operate 1,200 aircraft; and earn revenues in excess of $50 billion annually.

The express transportation industry specializes in time-definite, cost effective, reliable transportation services for documents, packages and freight and has solidified itself as an important contributor to the economic success of world economies. Express delivery has vital importance to businesses utilizing time-sensitive, "just-in-time" manufacturing techniques and supply-chain logistics in order to remain internationally competitive.

The courier industry relies heavily on the highest level of technology of any mode to control the movement of enormous volumes of time sensitive goods with tight delivery "cycle times," some using advanced targeting methods developed internationally, proven to intercept contraband and threats to security. For many years our industry has worked in close partnership with government agencies globally, whose prime objective is to support the delicate balance between trade facilitation and security.

The intent of the legislation and the procedures enacted as a result cannot be disputed, the CCMA supports the US FDA's goal towards defending the food supply which is a fundamental expectation of U.S. and Canadian citizens on the food imported into their respective countries, but the methods used to achieve this goal are imposing significant to potentially impossible administrative obstacles, we believe further FDA consultation with the trade community is necessary to ensure the procedures are workable. Towards that goal the CCMA submits the following answers to the questions posed in the Federal Register as well as comments for consideration.

Q: Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C-TPAT and FAST? If so, how should this be accomplished?

A: Food products subject to FDA's prior notice requirements should be eligible for the full expedited processing and information transmission benefits allowed with C-TPAT and FAST as the companies certified under C-TPAT and FAST have made the security investments and have bolstered their operations to provide the requisite security and integrity of their trade transactions.

Q: If the timeframe for submitting prior notice for food arriving by land via road is reduced to 1 hour consistent with the timeframe in the advance electronic information rule, would a shorter timeframe be needed for members of FAST?

A: Yes a shorter timeframe is needed for members of FAST, it would be critical to harmonize the Prior Notice timelines to the FAST and ACE transmission timelines, ensuring consistency and compliance of the trade community and efficiencies in both agency and industry workforces. This direction is reinforced by the fact that FDA is utilizing the CBP workforce to perform responsibilities. Ensuring consistency with FAST and ACE, the Prior Notice should be required and calculated from the port of entry and not the first point of arrival, as is currently the case.

Q: Should the security and verification processes in C-TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?

A: We see no benefits to USFDA in modification of the security and verification processes under C-TPAT. Companies certified under C-TPAT have made the critical security investments and have bolstered their operations to provide the requisite security and integrity of their trade transactions regardless of the commodities that are shipped, food or non-food products.

Q: Should FDA consider inspection of companies in the supply chain from the manufacturer to those who may hold the product, including reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities as a condition of participation?

A: We see no benefits to USFDA in consideration of inspection of companies in the supply chain dealing with food. Those certified under C-TPAT have already undergone security profiling and clearance, further inspection by FDA would equate to a duplication of effort by two different agencies.

Q: Are there conditions of participation that FDA should consider, e.g., inspections of companies in the supply chain from the manufacturer to those who may hold the product, reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities?

A: Those who pursue and gain C-TPAT certification have already undergone such review; this direction would be a repetition of effort with little return on investment.

Q: If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?

A: If the phase in plan for ACE under consideration by CBP is adopted, which is a port by port implementation according to a time schedule; this would be very problematic to industry. Systems and operations do not necessarily have the flexibility to switch on by individual site or location. In addition, the current plan would introduce complication and confuse the trade community. We would recommend further discussion with CBP and FDA as to development of a more viable and achievable implementation plan.

Q: Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?

A: Communication and training in any form on new initiatives is beneficial, it dispels misinformation and would augment the overall success and the data integrity of the program.

Waybill as Shipment Identifier
With the intent to simplify and make the requirements more manageable the data requirements should be reassessed. One data element should link all information secured by the prior notice which would be beneficial for locating the shipment in the event of a possible crisis. As all shipments that are moved are repeatedly covered by a waybill/bill of lading regardless of mode which is recognized by the entire trade chain and government, we suggest this number be utilized as a single reference point.

Removal of Redundant Information
The Prior Notification submission timelines should be based on electronic receipt by FDA with an acknowledgement sent back to the submitter. Usage of the waybill/bill of lading as the single reference point to the shipment instead of a prior notification number per FDA product commodity would render the secondary Prior Notification confirmation number now used and referenced to be redundant, adding benefits in reduced administration for all and easy traceability of the shipment should it be required.

In addition, if manufacturer and facility identification numbers are provided on the Prior Notification, and given the numbers provided are specific to a particular facility location, duplication should be eliminated by removing the requirement to complete the address information. As the manufacturer and facility identification numbers are not provided for homemade food or postal shipments, the necessity of providing this information for other types and modes should be examined.

In Transit Shipments
We feel an area of trade beyond the BTA's scope involves intransit goods traveling through the U.S. with no purpose of ever entering U.S. commerce. To accept the fact that goods entering and exiting the same U.S. port are more secure and therefore not subject to BTA requirements, while those that utilize more than one port, are not, is incongruent. It is highly unlikely that any of these shipments would be inadvertently delivered in the United States. Submitting prior notifications for transit food shipments presents a tremendous burden for our industry. All intransits are not intended for US consumption, are under strict Customs regulations and control by the carrier with respect to movement and are secured by a bond. It's unclear how prior notifications for transit shipments benefit the FDA or reduce the threat to public health, and we urge the FDA to exclude these shipments from BTA requirements.

U.S. Agents for Foreign Facilities
An element of the registration process that should be amended is the requirement of appointing a U.S. agent for foreign facilities. Considering the purpose of the emergency contact is for communication and notification purposes, requirements should be availability 24/7, intimate knowledge of the business, products and an ability to communicate in English. Engagement of a third party U.S. agent to act on a foreign businesses behalf will weaken the FDA's need for an accurate information exchange and a knowledgeable emergency personnel contact should it be required.

Notice Party
The party authorized to supply the notice to the FDA should be flexible including the Canadian exporter or authorized agent acting on behalf of the exporter or importer. This will reduce time delays, reflect reality, and will increase accuracy, to continue otherwise will result in U.S. buyers turning away from Canadian shippers and products due to increased administration and costs.

Gift Shipments
With the intent of the BTA legislation being to protect the nations' food supply we fail to see the rationale for reporting of "gift" food shipments. Person to person gift shipments of food have little potential to harm the nations' food chain as they are not distributed throughout the chain and hence cannot potentially impact large population centers which is what the BTA is intended to protect against. Using this logic we feel all "person to person" gift shipments of food should be exempted from these requirements regardless of whether they are commercially sourced or homemade by the shipper. Couriers and the Postal Service jointly carry a large portion of these types of shipments and compete for this business. Government must be diligent to ensure regulatory parity exists between these two modes to maintain a level playing field, otherwise market share loss for our industry caused by legislation will be the end result. Reporting requirements for personal shipments are adding needless cost, administration and complexity without tangible public protection benefits.

Personal Use Shipments
Small shipments of nominal value for personal, non-commercial use should be similarly exempted from the requirement for prior notification. The express industry handles many of these shipments now, which include purchases from a growing number of Internet-based sellers. Small shipments of this type for personal use do not qualify as a risk to the domestic food supply, and should therefore be considered outside the scope of the requirement for prior notification.

Prior Notice
Current Prior Notification data elements must be amended in order to make the FDA web portal viable. In most cases the shipper does not have access to complete information required of prior notice consisting of carrier, shipper and broker information which negates the advantage of a web reporting option. It becomes problematic to promote shipper compliance or avoid commerce impacts when the prime instrument shippers would use to report is largely unusable. The solution to this difficulty would be to enact consistency of data reporting across the board, meaning use of the Prior Notice data elements required of postal delivery for all modes.

Conflict Resolution
Considering the potential financial impacts to commerce should food shipments be detained needlessly, there should include a national level office/desk with the authority to resolve various field and port interpretations and actions that will occur as a result of the new legislation.

Penalty Options
With respect to the penalty provisions, there are few options available in the current penalty structure to assist FDA in enforcing compliance, other then civil and criminal charges. Some form of monetary consequences in lieu of charges should be available, to allow FDA more flexibility in application. It must be stated though, that failure to provide Prior Notification in a timely fashion should result in refused entry and the movement of the goods to a secure facility where the Prior Notification can be secured. Failure to enter the commerce should be considered sufficient deterrent and monetary penalties in this instance counter productive. This would avoid instances where businesses would find themselves unable to trade, or in a constant situation of being in violation, and consequently subject to criminal action.

In providing these comments the CCMA seeks a common and practical approach through working with the FDA that addresses the needs of the Bioterrorism act, yet does not impede or add cost to what has been a mutually beneficial and largely problem free trade between our two countries.

The CCMA ardently supports efforts to improve security of the U.S. food chain via the implementation of feasible initiatives that acknowledge trade facilitation requirements. We are pleased that the FDA indicates a willingness to inform and fully consider all comments. We believe the optimum method to achieve this worthy goal is through a stakeholder working group that can fully consider the ramifications of all facets of this matter and develop viable recommendations. We urge that this type of group could work toward achieving an industry supportable method of addressing USFDA requirements, aiding in its targeting efforts while balancing the economic realities of avoiding damage to the global economy with implementation on a practical prospective basis.

We appreciate the USFDA's consideration of these comments ensuring Canadian concerns are voiced and taken into consideration. I thank you in advance for your attention and consideration of our letter. If you have any questions I can be reached directly at 905 257 7027 or pcahley@canadiancourier.org

Sincerely,
Phil Cahley

Executive Director